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IX - 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Submitted by:

Tadeusz Wellisz, M.D.
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
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JAN 24 2007

Contact Person:	Tadeusz Wellisz, M.D.
Date Prepared	January 8, 2007
Common/Usual Name:	Bone Hemostasis Implant Material
Proprietary Name:	Ostene®, AOC™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste
Classification Name:	Bone Wax (Unclassified) ENT Synthetic Polymer Material (Class II)
Predicate Device:	Ceremed, Inc. Ostene® Bone Hemostasis Material K062280

Description of the device:
Ostene is an odorless, opaque wax-like material designed to be utilized directly out of the package. It is best used immediately following removal from the package, and can be softened and increased in stickiness by warming and by additional handling and manipulation, if so desired.

Ostene is comprised of a sterile mixture of water-soluble alkylene oxide copolymers, derived from ethylene oxide and propylene oxide. Ostene contains no other additives or colorants. The wax-like material is formed into sticks of various weights ranging from .5 to 5 grams each.

As a bone hemostasis agent, Ostene stops bone bleeding by the creation of a physical barrier along the edges of bones that have been damaged by trauma or cut during a surgical procedure. Ostene, when placed on bone under moderate pressure, plugs the vascular openings in the bone. This plug prevents further bleeding.

Ostene is provided sterile by irradiation and must not be resterilized.

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Intended use:
OSTENE is indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces.

Substantial equivalence:
The modified Ostene® Bone Hemostasis Material has the same intended use fundamental scientific technology as the legally marketed Ostene® Bone Hemostasis Material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ceremed Inc.
% Tadeusz Wellisz, M.D.
President
3643 Lenawee Avenue
Los Angeles, California 90016

JAN 2 4 2007

Re: K070093
Trade/Device Name: Ostene ® Soluble Bone Hemostasis Implant Material, AOC™, Ostene™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste™
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: II
Product Code: KHJ, MTJ
Dated: January 8, 2007
Received: January 10, 2007

Dear Dr. Wellisz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. INDICATIONS FOR USE:

510 (k) Number (if known): K070093

Device Name: Ostene® Soluble Bone Hemostasis Implant Material, AOC™, Ostene™, Osteotene™, Ceretene™, Cerepor™, Aptene™, Apatene™, Actipaste™

Indications For Use:
OSTENE® is indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070093